HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Menomune® – A/C/Y/W-135 vaccine safely and effectively. See full prescribing information for Menomune® – A/C/Y/W-135 vaccine.

Menomune® – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined
Solution for subcutaneous injection

Initial U.S. Approval: 1981

---------- INDICATIONS AND USAGE----------

- Menomune – A/C/Y/W-135 vaccine is a vaccine indicated for active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. Menomune – A/C/Y/W-135 vaccine is approved for use in persons 2 years of age and older. Menomune – A/C/Y/W-135 vaccine does not prevent *N meningitidis* serogroup B disease. (1)

---------- DOSAGE AND ADMINISTRATION ----------

- Single 0.5 mL subcutaneous injection. (2)

---------- DOSAGE FORMS AND STRENGTHS----------

- Menomune – A/C/Y/W-135 vaccine is supplied as a single dose or multidose (10 dose) vial of lyophilized vaccine, with corresponding single dose or multidose vial of diluent. After reconstitution of the lyophilized vaccine with the diluent, each dose consists of a 0.5 mL solution for injection. (3)

---------- CONTRAINDICATIONS----------

- Do not administer to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to Menomune – A/C/Y/W-135 vaccine or any component of the vaccine. (4)

---------- WARNINGS AND PRECAUTIONS ----------

- The stoppers to the vials of lyophilized vaccine and diluent contain dry natural latex rubber that may cause allergic reactions. (5.1)

---------- ADVERSE REACTIONS ----------

- Common (>10%) adverse events in children 2 to 10 years of age were injection site pain, drowsiness, irritability, and diarrhea. (6)
- Common (>10%) adverse events in persons 11 to 55 years of age were pain, redness, and induration at the injection site, headache, fatigue, malaise, arthralgia, and diarrhea. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

---------- DRUG INTERACTIONS----------

- Do not mix Menomune – A/C/Y/W-135 vaccine with other vaccines in the same syringe or vial. (7)
- Immunosuppressive therapies may reduce the immune response to Menomune – A/C/Y/W-135 vaccine. (7)
- No safety and immunogenicity data are available on the concomitant administration of Menomune – A/C/Y/W-135 vaccine with other US licensed vaccines. (7)

---------- USE IN SPECIFIC POPULATIONS ----------

- Pregnancy: No human or animal data. Use only if clearly needed. (8.1)
- Geriatrics: Not known whether persons aged 65 years and older respond differently from younger persons. (8.5)

See 17 for **Patient Counseling Information.**

Revised: [April 2013]

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FULL PRESCRIBING INFORMATION:

1. INDICATIONS AND USAGE

Menomune® – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined, is indicated for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. Menomune – A/C/Y/W-135 vaccine is approved for use in persons 2 years of age and older. Menomune – A/C/Y/W-135 vaccine does not prevent *N meningitidis* serogroup B disease.

2. DOSAGE AND ADMINISTRATION

2.1. Administration

The package contains a vial of lyophilized vaccine and a vial of diluent. The lyophilized vaccine should be a white or off-white color to a light beige color. The diluent used for reconstitution is a clear liquid.

After removing the "flip-off" caps, cleanse the vaccine and diluent vial stoppers with a suitable germicide. Do not remove the vial stoppers or metal seals holding them in place. Using a suitable sterile needle and syringe and aseptic technique, withdraw the supplied diluent (0.6 mL for single dose presentation and 6.0 mL for multidose presentation) (Refer to Figure 1) and inject into the vial containing the lyophilized vaccine (Refer to Figure 2). Swirl the vial until the vaccine is thoroughly dissolved (Refer to Figure 3). When reconstituted, the vaccine should be a clear, colorless liquid.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Using a suitable sterile needle and syringe and aseptic technique, withdraw (Refer to Figure 4) and administer a 0.5 mL dose of Menomune – A/C/Y/W-135 vaccine by subcutaneous injection. Use a separate sterile needle and syringe and aseptic technique for each dose withdrawn from the multidose vial.

Do not administer this product intravenously or intramuscularly.

The preferred site of administration is the deltoid region.

Menomune vaccine: Instructions for reconstitution

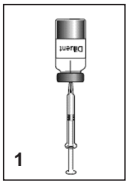

Figure 1
For the **single-dose presentation**, withdraw **0.6** mL of the supplied diluent; for the **multidose presentation**, withdraw **6.0** mL.

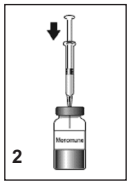

Figure 2
Insert the syringe needle through the stopper of the vial of lyophilized Menomune vaccine component and inject the diluent into the vial.

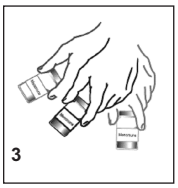

Figure 3
Swirl the vial until the lyophilized vaccine component is thoroughly dissolved.

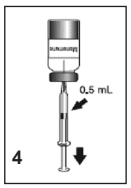

Figure 4
After reconstitution, withdraw 0.5 mL of Menomune vaccine and administer subcutaneously. Use the single-dose presentation immediately after reconstitution. The multidose presentation may be used for up to 35 days after reconstitution if stored at 2° to 8°C.

The vaccine should not be combined through reconstitution or mixed with any other vaccine.

Vaccine supplied in single dose vials should be used immediately after reconstitution. Vaccine supplied in multidose vials may be used for up to 35 days after reconstitution if stored at 2° to 8°C (35° to 46°F). [See *How Supplied/Storage and Handling* (16.2).]

2.2. Primary Immunization

Primary immunization with Menomune – A/C/Y/W-135 vaccine consists of a single 0.5 mL dose administered subcutaneously.

The ACIP (Advisory Committee on Immunization Practices) has specific recommendations for use of meningococcal vaccines. (1) (2) (3)

2.3. Revaccination

The ACIP has recommendations for revaccination against meningococcal disease for persons at high risk who were previously vaccinated with Menomune – A/C/Y/W-135 vaccine. (1) (3) If Menomune – A/C/Y/W-135 vaccine is used for revaccination, the dose is 0.5 mL administered subcutaneously.

3. DOSAGE FORMS AND STRENGTHS

Menomune – A/C/Y/W-135 vaccine is supplied as a lyophilized vaccine, in a single dose or a multidose (10 dose) vial, with corresponding single dose or multidose vial of diluent. The lyophilized vaccine is reconstituted with the diluent [see *Dosage and Administration* (2.1)]. After reconstitution, each dose consists of a 0.5 mL solution for injection. See *Description* (11) for the complete listing of ingredients.

4. CONTRAINDICATIONS

4.1. Hypersensitivity

Do not administer to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to Menomune – A/C/Y/W-135 vaccine or any component of the vaccine [see *Description* (11)].

5. WARNINGS AND PRECAUTIONS

5.1. Latex

The stoppers to the vials of lyophilized vaccine and diluent contain dry natural latex rubber that may cause allergic reactions in latex sensitive persons.

5.2. Management of Acute Allergic Reactions

Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3. Moderate or Severe Acute Illness

To avoid diagnostic confusion between manifestations of an acute illness and possible vaccine adverse effects, vaccination with Menomune – A/C/Y/W-135 vaccine should be postponed in persons with moderate or severe acute illness. (4)

5.4. Limitations of Vaccine Effectiveness

Menomune – A/C/Y/W-135 vaccine may not protect all recipients.

5.5. Altered Immunocompetence

Persons who are immunosuppressed, including persons receiving immunosuppressive therapy, may have a diminished immune response to Menomune – A/C/Y/W-135 vaccine [see *Drug Interactions* (7)].

6. ADVERSE REACTIONS

6.1. Data from Clinical Studies

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in clinical practice.

In three clinical trials primarily designed to assess the safety and immunogenicity of another vaccine, Menactra® [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], participants were randomized to receive Menactra or Menomune – A/C/Y/W-135 vaccine, which was used as a control vaccine. In these three trials, 1519 children 2-10 years of age, 972 persons 11-18 years of age, and 1170 adults 18-55 years of age, respectively, received a dose of Menomune – A/C/Y/W-135 vaccine. Overall, of the children 2-10 years of age who received Menactra or Menomune – A/C/Y/W-135 vaccine, 68% were enrolled at US sites and 32% were enrolled at a Chilean site. The median ages of US and Chilean children were 6 and 5 years, respectively; overall, 50.5% were males and 92.0% were Caucasian. Among participants 11-55 years of age who received Menactra or Menomune – A/C/Y/W-135 vaccine, all were enrolled at US sites; 54.8% were female; 87.7% were Caucasian.

Solicited local and systemic reactions were monitored daily for 7 days post-vaccination using a diary card. Information on serious adverse events was collected at interim clinic visits and by telephone interview conducted 6 months post-vaccination. At least 94% of participants from the three studies completed the 6-month follow-up.

Serious Adverse Events

Across the three studies, serious adverse events within 6-months following Menomune – A/C/Y/W-135 vaccine were reported in 0.7% of 1519 children 2-10 years of age, 0.6% of 972 persons 11-18 years of age, and 1.7% of 1170 persons 18-55 years of age.

Solicited Adverse Events[a]

The most commonly reported solicited adverse events in US children 2-10 years of age were injection site pain, irritability, and diarrhea. (Table 1)

The most commonly reported solicited adverse events in adolescents, ages 11-18 years, and adults, ages 18-55 years, were injection site pain, headache, and fatigue. (Table 2)

[a] Events in Table 1 and Table 2 were collected in the clinical trials under "Solicited local and systemic reactions."

Table 1: Percentage of US Participants 2-10 Years of Age Reporting Solicited Adverse Events Within 7 Days Following Administration of Menomune – A/C/Y/W-135 Vaccine

	N=1019-1027*		
Event	**Any**	**Moderate**	**Severe**
	%	**%**	**%**
General disorders and administration site conditions			
Injection site reaction			
Pain†	26.1	2.5	0.0
Redness‡	7.9	0.5	0.0
Induration‡	4.2	0.6	0.0
Swelling‡	2.8	0.3	0.0
Systemic events			
Fever§	5.2	1.7	0.2
Gastrointestinal disorders			
Anorexia‖	8.7	1.3	0.8
Vomiting¶	2.7	0.7	0.6
Diarrhea#	11.8	2.5	0.3
Nervous system disorders			
Drowsiness**	11.2	2.5	0.5
Irritability††	12.2	2.6	0.6
Seizures‡‡	0.0	N/A	N/A
Musculoskeletal and connective tissue disorders			
Arthralgia§§	5.3	0.7	0.0
Skin and subcutaneous disorders			
Rash‡‡	3.0	N/A	N/A

* N = The total number of participants with reported data. The N is 1027 for all solicited events except fever (N=1019). The percentage is based on N.

† Moderate: Discomforting, interfered with or limited usual arm movement, Severe: Disabling, child unable to move arm.

‡ Moderate: 1.0–2.0 inches; Severe: >2.0 inches.
§ Oral equivalent temperature; Moderate: 38.4-39.4ºC, Severe: ≥39.5ºC.
‖ Moderate: Skipped 2 meals, Severe: skipped ≥3 meals.
¶ Moderate: 2 episodes, Severe: ≥3 episodes.
# Moderate: 3-4 episodes, Severe: ≥5 episodes.
** Moderate: Interferes with normal activities, Severe: disabling, unwilling to engage in play or interaction with others.
†† Moderate: 1-3 hours duration, Severe: >3 hours duration.
‡‡ These solicited adverse events were reported as present or absent only.
§§ Moderate: Decreased range of motion due to pain or discomfort, Severe: unable to move major joints because of pain.

Table 2: Percentage of Participants 11-55 Years of Age Reporting Solicited Adverse Events Within 7 Days Following Administration of Menomune – A/C/Y/W-135 Vaccine

	Study 1 N*=970			Study 2 N*=1159		
	Participants 11-18 years of age			Participants 18-55 years of age		
Event	**Any**	Moderate	Severe	**Any**	Moderate	Severe
General disorders and administration site conditions						
Injection site reaction						
Pain†	**28.7**	2.6	0.0	**48.1**	3.3	0.1
Redness‡	**5.7**	0.4	0.0	**16.0**	1.9	0.1
Induration‡	**5.2**	0.5	0.0	**11.0**	1.0	0.0
Swelling‡	**3.6**	0.3	0.0	**7.6**	0.7	0.0
Systemic events						
Fatigue§	**25.1**	6.2	0.2	**32.3**	6.6	0.4
Malaise§	**16.8**	3.4	0.4	**22.3**	4.7	0.9
Chills§	**3.5**	0.4	0.1	**5.6**	1.0	0.0
Fever‖	**3.0**	0.3	0.1	**0.5**	0.1	0.0
Gastrointestinal disorders						
Diarrhea¶	**10.2**	1.3	0.0	**14.0**	2.9	0.3
Anorexia#	**7.7**	1.1	0.2	**9.9**	1.6	0.4
Vomiting**	**1.4**	0.5	0.3	**1.5**	0.2	0.4
Nervous system disorders						
Headache††	**29.3**	6.5	0.4	**41.8**	8.9	0.9
Seizure‡‡	**0.0**	N/A	N/A	**0.0**	N/A	N/A
Musculoskeletal and connective tissue disorders						
Arthralgia§	**10.2**	2.1	0.1	**16.0**	2.6	0.1
Skin and subcutaneous disorders						
Rash‡‡	**1.4**	N/A	N/A	**0.8**	N/A	N/A

* N=Total number of participants with data.
† Moderate: Discomforting, interfered with or limited usual arm movement, Severe: Disabling, unable to move arm.
‡ Moderate: 1.0–2.0 inches; Severe: >2.0 inches.
§ Moderate: Interferes with normal activities, Severe: disabling, requires bed rest.
‖ Oral equivalent temperature. Study 1: Moderate: 38.5-39.4ºC, Severe: ≥39.5ºC. Study 2: Moderate 39.0-39.9ºC, Severe: ≥40.0ºC.
¶ Moderate: 3-4 episodes, Severe: ≥5 episodes.
# Moderate: Skipped 2 meals, Severe: skipped ≥3 meals.
** Moderate: 2 episodes, Severe: ≥3 episodes.
†† Moderate: discomforting enough to interfere with activities, Severe: disabling requires bed rest and analgesics.
‡‡ These solicited adverse events were reported as present or absent only.

6.2. Data from Post-Marketing Experience

The following adverse events have been spontaneously reported during post-approval use of Menomune – A/C/Y/W-135 vaccine since 1993 through November 2008. Because these events were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to Menomune – A/C/Y/W-135 vaccine exposure.

The following adverse events were included based on severity, frequency of reporting or the strength of causal association to Menomune – A/C/Y/W-135 vaccine.

- Immune System Disorders
  Hypersensitivity, such as rash, urticaria, pruritus, dyspnea, angioedema
- Nervous System Disorders
  Headache, vasovagal syncope, dizziness, paresthesia, Guillain-Barré syndrome
- Gastrointestinal Disorders
  Nausea, vomiting, diarrhea
- Musculoskeletal and Connective Tissue Disorders
  Myalgia, arthralgia
- General Disorders and Administration Site Conditions
  Fever, injection site reaction, malaise, asthenia, chills, fatigue

7. DRUG INTERACTIONS

Separate syringes and injection sites must be used in case of concomitant administration.

Do not mix Menomune – A/C/Y/W-135 vaccine with other vaccines in the same syringe or vial.

Immunosuppressive therapies may reduce the immune response to Menomune – A/C/Y/W-135 vaccine.

No safety and immunogenicity data are available on the concomitant administration of Menomune – A/C/Y/W-135 vaccine with other US licensed vaccines.

8. USE IN SPECIFIC POPULATIONS

8.1. Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Menomune – A/C/Y/W-135 vaccine. It is also not known whether Menomune – A/C/Y/W-135 vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Menomune – A/C/Y/W-135 vaccine should be given to a pregnant woman only if clearly needed.

8.3. Nursing Mothers

It is not known whether Menomune – A/C/Y/W-135 vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Menomune – A/C/Y/W-135 vaccine is administered to a nursing woman.

8.4. Pediatric Use

Safety and effectiveness of Menomune – A/C/Y/W-135 vaccine in children below the age of 2 years have not been established.

During a meningococcal serogroup A epidemic in sub-Saharan Africa, children 3 months to 16 years of age were vaccinated with a high molecular weight serogroup A/C meningococcal polysaccharide vaccine. In case-control studies, after 1 year of observation, vaccine efficacy against meningococcal serogroup A disease was estimated to be 87% [90% Confidence Interval (CI), 52% to 96%], overall. After 3 years, efficacy was estimated to be 67% (90% CI, 40% to 82%) among children who were 4-16 years of age at the time of vaccination and 8% (90% CI, -102% to 58%) among children who were 1-3 years of age at the time of vaccination. (5)

The efficacy of a serogroup C meningococcal vaccine in infants and young children was evaluated in a placebo-controlled trial during a serogroup C epidemic in Brazil. Vaccine efficacy was estimated to be 12% (95% CI, -55% to 62%) among children 6 to 23 months of age and 55% (95% CI, -4% to 72%) among children 24 to 36 months of age. (6)

8.5. Geriatric Use

Clinical studies of Menomune – A/C/Y/W-135 vaccine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

11. DESCRIPTION

Menomune – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined, is a vaccine for subcutaneous injection. Menomune – A/C/Y/W-135 vaccine consists of a sterile lyophilized preparation of the group-specific polysaccharide antigens from *N meningitidis*, Group A, Group C, Group Y, and Group W-135. *N meningitidis* are cultivated on Mueller Hinton casein agar (7) and grown in Watson Scherp casamino acid media (8). The purified polysaccharide is extracted from the *N meningitidis* cells and separated from the media by procedures which include centrifugation, detergent precipitation, alcohol precipitation, solvent or organic extraction, and diafiltration. No preservative is added during manufacture.

The diluent (0.6 mL) for the single dose presentation contains sterile, pyrogen-free distilled water without preservative. The diluent (6 mL) for the multidose presentation contains sterile, pyrogen-free distilled water and thimerosal, a mercury derivative, which is added as a preservative for the reconstituted vaccine. [See *How Supplied/Storage and Handling* (16).]

After reconstitution with diluent, the vaccine is a clear colorless liquid solution. Each 0.5 mL dose contains 50 mcg of polysaccharide from each of serogroups A, C, Y, and W-135. Reconstituted vaccine from a multidose vial also contains 25 mcg mercury per dose.

Each dose of vaccine contains 2.5 mg to 5 mg of lactose added as a stabilizer. (9)

Potency is evaluated by measuring the molecular size of each polysaccharide component using a column chromatography method as standardized by the US Food and Drug Administration (FDA) and the World Health Organization (WHO) (10) for Meningococcal Polysaccharide Vaccine.

12. CLINICAL PHARMACOLOGY

12.1. Mechanism of Action

The presence of bactericidal anti-capsular meningococcal antibodies has been associated with protection from invasive meningococcal disease. (11) (12) Menomune – A/C/Y/W-135 vaccine induces the production of bactericidal antibodies specific to the capsular polysaccharides of serogroups A, C, Y, and W-135.

13. NON-CLINICAL TOXICOLOGY

13.1. Carcinogenesis, mutagenesis, impairment of fertility

Menomune – A/C/Y/W-135 vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

14. CLINICAL STUDIES

Effectiveness of Menomune – A/C/Y/W-135 vaccine was inferred by evaluating the proportion of children 2-10 years of age achieving a pre-specified level of serum bactericidal antibody and the proportion of persons 11-55 years of age achieving a 4-fold increase from baseline in serum bactericidal antibody, for each serogroup. Evidence for clinical efficacy against serogroup- specific meningococcal disease in school-age children and adults has been obtained from historical field trials and observational studies with other high molecular weight polysaccharide vaccines containing meningococcal serogroup A and/or C components. (6) No studies have been conducted to evaluate the efficacy of meningococcal polysaccharide vaccines against disease due to serogroups Y and W-135.

Menomune – A/C/Y/W-135 vaccine was used as the control vaccine in three US, multi-center, clinical trials designed primarily to evaluate the immunogenicity and safety of Menactra vaccine in children (2-10 years old), adolescents (11-18 years old), and adults

(18-55 years old), respectively. In these trials, participants in the control arm received a dose of Menomune – A/C/Y/W-135 vaccine. Sera were obtained before and approximately 28 days after vaccination. The Serum Bactericidal Assay (SBA) used to test sera contained an exogenous complement source that was either human (SBA-H) or, when correlated to SBA-H, baby rabbit (SBA-BR). (13)

Data on immune responses, as measured by SBA-H, following Menomune – A/C/Y/W-135 vaccine in a subset of children 2-10 years old are presented in Table 3. Data on immune responses, as measured by SBA-BR, following Menomune – A/C/Y/W-135 vaccine in adolescents and adults are presented in Table 4.

Table 3: Bactericidal Antibody Responses* to Menomune – A/C/Y/W-135 Vaccine 28 Days After Vaccination for Subsets of Participants Aged 2-3 and 4-10 Years

Menomune – A/C/Y/W-135 vaccine Aged 2-3 Years N†=50-53				Menomune – A/C/Y/W-135 vaccine Aged 4-10 Years N†=84			
Serogroup			**(95% CI)‡**	**Serogroup**			**(95% CI)‡**
A	% ≥1:8	64	50,77	**A**	% ≥1:8	55	44,66
	GMT	10	7,12		GMT	7	6,9
C	% ≥1:8	38	25,53	**C**	% ≥1:8	48	37,59
	GMT	11	5,21		GMT	12	7,18
Y	% ≥1:8	73	59,84	**Y**	% ≥1:8	92	84,97
	GMT	18	11,27		GMT	46	33,66
W-135	% ≥1:8	33	20,47	**W-135**	% ≥1:8	79	68,87
	GMT	5	3,6		GMT	20	14,27

The study was designed to show the safety and immunogenicity of Menactra vaccine are non-inferior to that of Menomune – A/C/Y/W-135 vaccine. The table shows the immune response in Menomune – A/C/Y/W-135 vaccine participants from this study.

* Serum Bactericidal Assay with an exogenous human complement (SBA-H) source.
† N = Number of subset participants with at least one valid serology result at Day 0 and Day 28.
‡ The 95% CI for the Geometric Mean Titer (GMT) was calculated based on an approximation to the normal distribution.

In participants 2-3 years of age with undetectable pre-vaccination SBA titers (ie, <4 at Day 0), rates of seroconversion (defined as SBA titer ≥8 at Day 28) following Menomune – A/C/Y/W-135 vaccine were 55%, serogroup A (n=16/29); 30%, serogroup C (n=13/43); 57%, serogroup Y (n=17/30); 26%, serogroup W-135 (n=11/43).

In participants 4-10 years of age with undetectable pre-vaccination SBA titers (ie, <4 at Day 0), rates of seroconversion (defined as SBA titer ≥8 at Day 28) following Menomune – A/C/Y/W-135 vaccine were 48%, serogroup A (n=10/21); 38%, serogroup C (n=19/50); 84%, serogroup Y (n=38/45); 68%, serogroup W-135 (n=26/38).

Table 4: Bactericidal Antibody Responses* to Menomune – A/C/Y/W-135 Vaccine 28 Days After Vaccination for Participants Aged 11-18 and 18-55 Years

Menomune – A/C/Y/W-135 vaccine Aged 11-18 Years N†=423				Menomune – A/C/Y/W-135 vaccine Aged 18-55 Years N†=1098			
Serogroup			**(95% CI)‡**	**Serogroup**			**(95% CI)‡**
A	% ≥4-fold rise§	92.4	(89.5, 94.8)	**A**	% ≥4-fold rise§	84.6	(82.3, 86.7)
	GMT	3246	(2910, 3620)		GMT	4114	(3832, 4417)
C	% ≥4-fold rise§	88.7	(85.2, 91.5)	**C**	% ≥4-fold rise§	89.7	(87.8, 91.4)
	GMT	1639	(1406, 1911)		GMT	3469	(3148, 3823)
Y	% ≥4-fold rise§	80.1	(76.0, 83.8)	**Y**	% ≥4-fold rise§	79.4	(76.9, 81.8)
	GMT	1228	(1088, 1386)		GMT	2449	(2237, 2680)
W-135	% ≥4-fold rise§	95.3	(92.8, 97.1)	**W-135**	% ≥4-fold rise§	94.4	(92.8, 95.6)
	GMT	1545	(1384, 1725)		GMT	1871	(1723, 2032)

Both studies (11-18 and 18-55 years of age) were designed to show the safety and immunogenicity of Menactra vaccine are non-inferior to that of Menomune – A/C/Y/W-135 vaccine. The table shows the immune response in Menomune – A/C/Y/W-135 vaccine participants from these studies.

* Serum Bactericidal Assay with baby rabbit complement (SBA-BR).
† N = Number of participants with valid serology results at Day 0 and Day 28.
‡ The 95% CI for the GMT was calculated based on an approximation to the normal distribution.
§ The proportion of subjects with a ≥4-fold rise from baseline in SBA-BR titer for *N meningitidis* for each of the serogroups A, C, Y and W-135, 28 days following vaccination with Menomune – A/C/Y/W-135 vaccine.

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In participants 11-18 years of age with undetectable pre-vaccination SBA titers (ie, <8 at Day 0), rates of seroconversion (defined as a ≥4-fold rise in Day 28 SBA titers) following Menomune – A/C/Y/W-135 vaccine were 100%, serogroup A (n=93/93); 99%, serogroup C (n=151/152); 100%, serogroup Y (n=47/47); 99%, serogroup W-135 (n=138/139).

In participants 18-55 years of age with undetectable pre-vaccination SBA titers (ie, <8 at Day 0), rates of seroconversion (defined as a ≥4-fold rise in Day 28 SBA titers) following Menomune – A/C/Y/W-135 vaccine were 99%, serogroup A (n=143/144); 98%, serogroup C (n=297/304); 97%, serogroup Y (n=221/228); 99%, serogroup W-135 (n=325/328).

15. REFERENCES

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16. HOW SUPPLIED/STORAGE AND HANDLING

16.1. How Supplied

One single dose vial of lyophilized vaccine (NDC 49281-487-58) with one 0.6 mL vial of diluent (NDC 49281-466-08) (contains no preservative). Supplied as package NDC 49281-489-01.

One 10 dose vial of lyophilized vaccine (NDC 49281-488-78) with one 6.0 mL vial of diluent (NDC 49281-466-91) (contains preservative). Supplied as package NDC 49281-489-91.

16.2. Storage

Store lyophilized vaccine, diluent, and reconstituted vaccine, when not in use, at 2° to 8°C (35° to 46°F). Do not freeze.

Do not use after the expiration date shown on the vial labels of the lyophilized vaccine and diluent.

Discard remainder of reconstituted vaccine from multidose vials within 35 days after reconstitution. Vaccine from single dose vials should be used immediately after reconstitution.

17. PATIENT COUNSELING INFORMATION

Before administration of Menomune – A/C/Y/W-135 vaccine, health-care providers should inform the patient, parent or guardian of the benefits and risks of the vaccine. The health-care provider should provide the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given with each immunization. Patients, parents, or guardians should be instructed to report adverse reactions to their health-care provider.

Rx only

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